Remplir™ nerve repair device receives Australian regulatory approval

- **Orthocell receives Australian regulatory (TGA) approval** for Remplir™ for use in peripheral nerve repair procedures
- **Remplir™ nerve repair device represents a paradigm shift** in product design and application to facilitate the regeneration of damaged peripheral nerves
- **Significant Australian addressable market,** with 11,780[1] surgical repairs of peripheral nerves completed in public and private hospitals in the 2019/20 financial year
- **Australian reimbursement application planned for Q2 CY2022** which defines the minimum benefit value private insurers pay for Remplir™
- **Approval validates the CelGro® platform technology** and positions Orthocell well to achieve further international regulatory approvals in nerve repair

Perth, Australia; 21 March 2022: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce Australian market approval for its Remplir™ peripheral nerve repair device, for introduction into the Australian nerve repair and regeneration market.

Orthocell Managing Director Paul Anderson, said: "Remplir™ is the first of its kind biological scaffold designed by an Australian team of researchers to mimic the outer layer of the peripheral nerve and facilitate high quality nerve repair. Remplir™ is the only Australian manufactured medical device for nerve repair to gain Australian regulatory approval and is a significant inflection point for our Company. This is an important step on our continued pathway to making a meaningful impact in the global market."

Inclusion of Remplir™ on the Australian Register of Therapeutic Goods (ARTG) follows successful Conformity Assessment by the TGA with respect to the evaluation of the safety and performance of Remplir™ in peripheral nerve repair. The Company is now focused on achieving reimbursement by insurers and has progressed its application for inclusion on the Prostheses List. Application for inclusion on the Prostheses List is planned for submission in Q2 CY2022.

The Australian market entry strategy involves expanding the Key Opinion Leader network using Remplir™ in peripheral nerve repair procedures and potentially engaging a high quality distributor. This strategy will assist in establishing Remplir™ as the leading nerve repair device. A product awareness program was launched at the 2022 Australian Hand Surgery Society Annual Scientific Meeting, where pre-clinical and clinical data was presented. This will be followed with another presentation at the 2022 Shoulder and Elbow Society Australia Biennial Conference in Sydney from 31 March to 03 April 2022.

The Remplir™ Advantage

Remplir™ is manufactured by Orthocell at its GMP (Good Manufacturing Practice) facility in WA, using the Company's proprietary SMRT™ manufacturing technology. This technology was developed in conjunction with Professor Minghao Zheng, the University of Western Australia and the Perron Institute.

[1] The Australian Institute of Health and Welfare, https://www.aihw.gov.au/reports-data/myhospitals

Professor Minghao Zheng, of University of Western Australia, Perron Institute of Neurological and Translational Research and Orthocell Chief Scientific Officer, said: "Remplir™ represents a paradigm shift in product design and application**.** It provides a barrier structure to protect the nerve and generates an ideal microenvironment for the regeneration of damaged peripheral nerves. Remplir™ reduces the need for suturing, is easy to use and results in consistent and predictable return of muscle function to paralysed limbs. This will empower surgeons to improve the lives of patients with complex nerve injuries[2]."

The Australian addressable market is significant, with 11,7801 surgical repairs of peripheral nerves completed in public and private hospitals in the 2019/20 financial year. The Company believes Remplir™ will become the market leading nerve repair device, with uptake driven by the surgeon's preference for high quality, easy to use devices that reduce the need for damaging sutures and facilitates better patient outcomes (Figure 1).

Clinical studies have shown nerve repair with Remplir™ consistently restores arm and hand function. Interim results to date of patients in Orthocell's nerve repair clinical study showed **82.6% (19 of 23) of nerve repairs with Remplir™, at 24 months post treatment, resulted in functional recovery of muscles controlled by the repaired nerve**. These interim results are a continuation of the clinical study announced previously on 21 June 2021 (refer to ASX announcement). This is of significant interest to patients and clinicians due to potential improvement in efficiency and efficacy of nerve repair procedures.

The Company is well-positioned to achieve further international approvals for Remplir™ in nerve repair – a key growth area for our business.

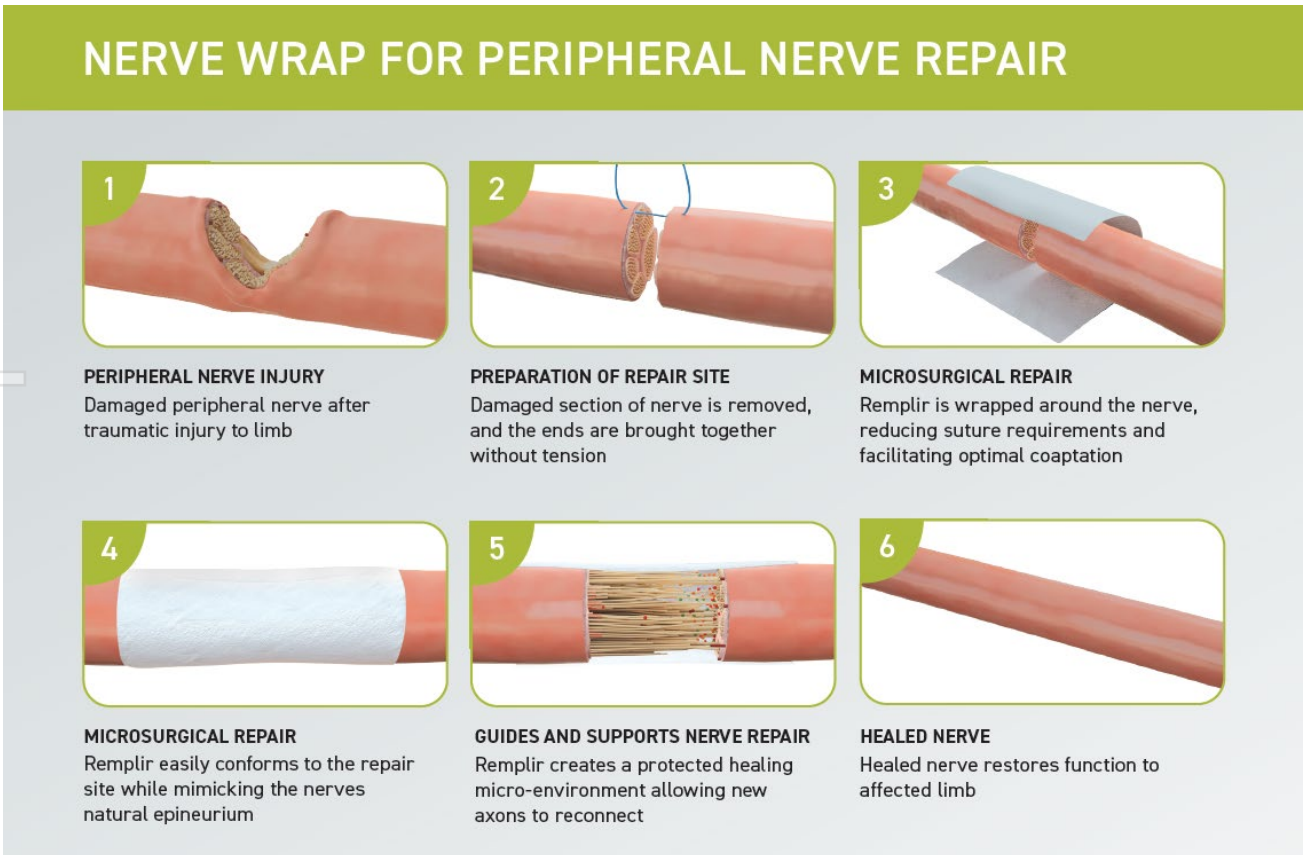

Figure 1: Remplir™ nerve wrap procedure

[2] Orthocell data presentation at the 2022 Australian Hand Surgery Society Annual Scientific Meeting

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About Orthocell Limited

Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries. Orthocell's portfolio of products include CelGro™, a collagen medical device which facilitates tissue repair and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications and is cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark). Remplir™, for peripheral nerve repair, recently received approval in Australia (ARTG). SmrtGraft™, for tendon repair, is available in Australia under Special Access Scheme or participation in a clinical trial. The Company's other major products are autologous cell therapies which aim to regenerate damaged tendon and cartilage tissue. Orthocell is accelerating the development of its tendon cell therapy in the US with technology transfer, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

For more information on Orthocell, please visit www.orthocell.com.au or follow us on Twitter **@Orthocellltd** and LinkedIn www.linkedin.com/company/orthocell-ltd

Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate, "expect," "intend," "may," "plan," "predict," "project," "target, "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.